

Claims:

1. A nucleic acid assay process comprising the steps of
amplifying a particular region of an analyte nucleic acid in
5 a specimen to prepare a double stranded sample DNA; adding
an excessive amount of said sample DNA to a labeled standard
DNA comprising a double stranded nucleic acid having a site
capable of binding to a solid support on one strand and a
detectable label on the other strand to allow competitive
10 hybridization to take place; and detecting the rehybridized
labeled standard DNA by utilizing said detectable label and
said site capable of binding to a solid support to thereby
evaluate the degree of exchange of the complementary strands
between said sample DNA and said labeled standard DNA for
15 detecting the target DNA which is the same as said labeled
standard DNA and which is present in said sample DNA;
characterized in that

a detection limit for the target DNA which is the same
as said labeled standard DNA and which is present in said
20 sample DNA is preliminarily selected, and excessiveness of
said sample DNA added to said labeled standard DNA in the
competitive hybridization is selected in accordance with the
thus selected detection limit.

2. A nucleic acid assay process according to claim 1
wherein, when the detection limit for the target DNA which
is the same as said labeled standard DNA and which is
present in said sample DNA is A/B , the excessiveness of said
sample DNA is at least B/A .

3. A nucleic acid assay process according to claim 1 ~~or 2~~
wherein the target DNA which is the same as said labeled
standard DNA and which is present in said sample DNA is
quantitated by utilizing theoretical values of the degree of
35 exchange of the complementary strands between said sample
DNA and said labeled standard DNA at the selected
excessiveness of said sample DNA.

4. A nucleic acid assay process according to ~~any one of~~ ^{claim 1} ~~claims 1 to 3~~ wherein the analyte nucleic acid is a cancer-related gene, a gene related to genetic disease, a virus gene, a bacteria gene, or a polymorphic host gene.

5. A nucleic acid assay process according to ~~any one of~~ ^{claim 1} ~~claims 1 to 4~~ wherein the analyte nucleic acid is k-ras gene, N-ras gene, p53 gene, BRCA1 gene, BRCA2 gene, or APC gene which is a cancer-related gene.

6. A nucleic acid assay process according to ~~any one of~~ ^{claim 1} ~~claims 1 to 5~~ wherein the sample DNA is the one which has been gene amplified by using a pair of primers.

7. A nucleic acid assay process according to ~~any one of~~ ^{claim 1} ~~claims 1 to 6~~ wherein the labeled standard DNA is the one prepared by gene amplification using a primer having introduced therein a detectable label and a primer having introduced therein a region capable of binding to a solid support.

8. A nucleic acid assay process according to ~~any one of~~ ^{claim 1} ~~claims 1 to 6~~ wherein the labeled standard DNA is the one prepared by chemical synthesis.

9. A nucleic acid assay kit for assaying a nucleic acid in accordance with the nucleic acid assay process of ~~any one of~~ ^{claim 1} ~~claims 1 to 8~~, characterized in that said kit includes a labeled standard DNA comprising a double stranded nucleic acid having a site capable of binding to a solid support on one strand and a detectable label on the other strand.

10. A nucleic acid assay kit according to claim 9 comprising

a pair of primers for amplifying a particular region of an analyte nucleic acid in a specimen;

reagents for amplifying the particular region of the
analyte nucleic acid in the specimen by using said primers
to prepare the sample DNA;

- 5 a support for trapping the hybridizate; and
a reagent for detecting the hybridizate.

add B2

add C2

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H5

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